OCT 0 4 2002 K023049

510(k) Summary
SYNCHRON LX®i 725 System

1.0 Submitted By:

Mary Beth Tang
Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
Brea, CA 92822-8000
Telephone: (714) 961-3777
FAX: (714) 961-4123

2.0 Date Submitted

September 12, 2002

3.0 Device Name(s):

3.1 Proprietary Names:
SYNCHRON LX®i 725 System

3.2 Classification Names:
Discrete photometric chemistry analyzer for clinical use [862.2160]

4.0 Legally Marketed Device

The SYNCHRON LXi 725 System claims substantial equivalence to the SYNCHRON LX®20 PRO System currently in commercial distribution (Docket Number K011213).

5.0 Device Description

The SYNCHRON LXi 725 System combines the SYNCHRON LX20 PRO analyzer and Access®2 Immunoassay analyzer into a single instrument presentation. Samples are loaded from a single point of entry through the Closed Tube Aliquoter (CTA) connector unit. The CTA functions as a sample processing manager by aliquotting and routing samples to the Access 2 and/or LX20 PRO modules according to programming requirements. The LX20 PRO and Access 2 systems then deliver samples to the appropriate reaction vessel along with reagents and reaction constituents. The LX20-based console functions as the single user interface for managing routine operations such as sample programming, results management, and QC functions.

The LXi system provides analysis of up to 65 analytes per sample, operating in conjunction with the existing reagents, calibrators, and controls designed for use with the LX20 PRO and Access 2 analyzers. The instrument features bar code identification of samples and reagents, Closed Tube Sampling (CTS), and obstruction detection and correction capability. LXi system components include the LX20 PRO analyzer and console, the CTA module, and the Access 2 module and console. The subsystem hardware components for the analytical units include reagent storage compartments, sample and reagent delivery systems, cap piercing assemblies, sample carousels and cranes, hydropneumatics, fluidics, photometric detectors, electronics, and power supplies.

The LXi configuration incorporates the following upgrades to the LX20 PRO System:

1. Closed Tube Aliquotter (CTA) Module
The CTA serves as the connector between the Access 2 and LX20 PRO systems. The CTA module performs sample identification, aliquot preparation, and sample routing according to programming requirements. The CTA uses disposable aliquot vessels for Access 2 sampling. The key hardware components include a laser bar code reader, sample rack shuttle, cap piercer, aliquot probe, sample wheel, wash station, and gantry.

2. Access 2 Immunochemistry Module (previously reviewed/cleared under K922823)
The Access 2 analyzer expands the chemistry menu of the LX20 PRO System. An additional serial communications line allows remote control of the Access 2 instrument through the LX20-based console.

3. Hardware Modifications
The LX20 PRO sample rack shuttle and instrument covers have been modified to accommodate the CTA and Access 2 modules and to visually integrate the system.

4. Software Modifications
The LXi System utilizes LX20 operating software version 3.0. Version 3.0 contains the information necessary to configure, order, and report results for Access 2 tests.

6.0 Intended Use

The SYNCHRON LX®i 725 System combines the SYNCHRON LX®20 PRO analyzer and the Access®2 analyzer into a single instrument presentation. Samples are loaded from a single point of entry through a Closed Tube Aliquotter (CTA) unit. The CTA functions as a sample processing manager by aliquotting and routing samples to the Access 2 and/or LX20 PRO analyzer according to programming requirements.

The SYNCHRON LX20 PRO is a fully automated, computer-controlled clinical chemistry analyzer intended for the in vitro determination of a variety of general chemistries, therapeutic drugs, and other chemistries of clinical interest in biological fluids such as serum, plasma, urine, or cerebrospinal fluid, (sample type is chemistry dependent).

The Access 2 Immunoassay Analyzer is a microcomputer controlled, random access instrument. The analyzer performs enzyme immunoassays utilizing paramagnetic particle solid phase and chemiluminescent detection. The Access 2 Analyzer is intended for the in vitro determination of a variety of analytes of clinical interest in biological fluids such as serum, plasma, urine, and cerebral spinal fluid, (sample type is chemistry dependent).

7.0 Comparison to the Predicate

The SYNCHRON LX20 PRO system has been upgraded to an LXi system through 1) modifications to the sample rack shuttle and instrument covers, 2) the addition of a pre-analytical CTA unit and an Access 2 Immunoassay analyzer, and, 3) a software update to version 3.0. There is also a name change to LXi 725 System.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

Section 1: ADMINISTRATIVE INFORMATION

1.0 Submitted By:

Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
Brea, CA 92822-8000

Primary Contact:
Mary Beth Tang, Regulatory Affairs Specialist
Telephone: (714) 961-3777
FAX: (714) 961-4123
E-mail: mtang@beckman.com

Secondary Contact:
Annette Hellie, Regulatory Affairs Manager
Telephone: (714) 993-8767
FAX: (714) 961-4123

2.0 Sponsor Address/FDA Registration Number

Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
Brea, CA 92822-8000
Establishment Registration No. 2050012

3.0 Product Name/Classification Name and Number

Proprietary Names

SYNCHRON LX®i 725 System

Classification Names

Discrete photometric chemistry analyzer for clinical use [862.2160]

4.0 Device Classification

FDA has classified clinical chemistry test systems of this type into Class I (reserved)

5.0 Section 514 Compliance

This Special 510(k): Device Modification submission is prepared pursuant to the FDA publication: The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications – Issue Date: March 20, 1998.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Mary Beth Tang
Regulatory Affairs Specialist
Beckman Coulter, Inc.
200 S. Kraemer Blvd.
M/S W-104
Box 8000
Brea, CA 92822-8000

OCT 0 4 2002

Re: k023049
Trade/Device Name: SYNCHRON LX®I 725 System
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: Class II
Product Code: JGS; CHH, CDZ, CEO, DIH, JHB, JIF, JIY, JMO, CDD, CDP, CDQ, CEC, CEE, CEK, CEM, CFJ, CFR, CGA, CGR, CGS, CGX, CGZ, CIN, CJE, CJW, CZP, DCF, DCK, DDC, DDG, DDR, DEW, DFT, DGC, DHR, DIO, DIS, DJG, DJR, DKJ, DKZ, DLZ, DMT, GTQ, JFJ, JFL, JFM, JFP, JGS, JHI, JHW, JHX, JLW, JMG, JXM, KLI, KLS, KLT, KXS, KXT, LCD, LCM, LCP, LCR, LDJ, LDP, LEG, DHX, LFX, LGD, LJC, MRR, MSJ, MSW
Dated: September 12, 2002
Received: September 13, 2002

Dear Ms. Tang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: **SYNCHRON LX®i 725 System**

Indications for Use:

The SYNCHRON LX®i 725 System combines the SYNCHRON LX®20 PRO analyzer and the Access® 2 analyzer into a single instrument presentation. Samples are loaded from a single point of entry through a Closed Tube Aliquotter (CTA) unit. The CTA functions as a sample processing manager by aliquotting and routing samples to the Access 2 and/or LX20 PRO analyzer according to programming requirements.

The SYNCHRON LX20 PRO is a fully automated, computer-controlled clinical chemistry analyzer intended for the in vitro determination of a variety of general chemistries, therapeutic drugs, and other chemistries of clinical interest in biological fluids such as serum, plasma, urine, or cerebrospinal fluid, (sample type is chemistry dependent).

The Access 2 Immunoassay Analyzer is a microcomputer controlled, random access instrument. The analyzer performs enzyme immunoassays utilizing paramagnetic particle solid phase and chemiluminescent detection. The Access 2 Analyzer is intended for the in vitro determination of a variety of analytes of clinical interest in biological fluids such as serum, plasma, urine, and cerebral spinal fluid, (sample type is chemistry dependent).

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023049

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96